

**Remarks**

The Office action mailed November 28, 2007, has been reviewed and carefully considered. Claim 5 has been amended to provide a correct alphabetical order. Claims 55-63 have been amended because applicants' September 4, 2007, response inadvertently included two claims numbered "54". Entry of these amendments is respectfully requested since they do not raise any new issues and are directed to minor matters.

*35 U.S.C. §112, second paragraph, rejection*

The amendment of claim 5 obviates this rejection.

*35 U.S.C. §103 rejection*

Claims 1-6, 8-22, 34-46 and 49-62 have been rejected for obviousness under 35 U.S.C. §103 over Alkan et al. combined with Welkos et al. and Pozsgay et al. Claims 47 and 48 are not mentioned in the obviousness rejection, but the Office Action Summary sheet indicates that they are also rejected. If the examiner persists in this rejection, clarification of the status of claims 47 and 48 is respectfully requested.

Independent claim 1

The final OA on page 4 states that "Pozsgay et al. teach optimal immunogenicity for conjugates when polymers of hapten moieties are used." This interpretation of Pozsgay et al. reads something into Pozsgay et al. that simply is not there. The Pozsgay et al. teaching is limited to polysaccharide hapten conjugates. At most, Pozsgay et al. "suggest that the synthetic approach may be applicable to all polysaccharide-based vaccines" (page 5196, column 2, end of third full paragraph). The conjugate of claim 1 comprises a synthetic homopolymer of poly- $\gamma$ -glutamic acid ( $\gamma$ PGA) *polypeptide* covalently linked to a carrier. Teachings regarding a polysaccharide-based

vaccine cannot reasonably be inferred to a polypeptide-based vaccine. The examiner has not provided any rational basis for generalizing the limited teachings of Pozsgay et al. to apply to all types of immunogenic conjugates. The lack of such a rational basis is especially problematic in an unpredictable field such as immunology.

#### Independent claim 5

Claim 5 lists several specific carriers. Alkan et al. discloses a conjugate that includes L-tyrosine-azobenzeneearsonate (RAT) linked to PGA. There is no teaching in Alkan et al, Welkos et al. or Pozsgay et al. that the specific carriers of claim 5 could be substituted for the RAT carrier of Alkan et al. Accordingly, the obviousness rejection of claim 5 must be withdrawn.

#### Claims 13, 14, and 57-63

Applicants' September 4, 2007, response pointed out on pages 12-13, that there is a marked difference in the chemical structure of the Alkan et al. conjugate and the conjugate presently recited in claims 13, 14 and 57-62. The final OA does not appear to respond to this argument, and does not address the separate basis for patentability of claims 13, 14 and 57-63. In particular, the conjugates of these claims include a plurality of  $\gamma$ PGA polypeptide chains per carrier molecule (see, e.g., page 15, lines 28-38 of the present application). In contrast, the Alkan et al. construct includes a plurality of RAT molecules (carrier) linked to a single PGA molecule (see the Abstract – “an average of nine molecules of RAT were linked directly to the PGA backbone [PGA-(RAT)<sub>9</sub>]” and page 358, first column, “The use of PGA-RAT conjugates reversed the customary small hapten-large carrier relationship, and resulted in conjugates that bore multiple carrier moieties”). Furthermore, RAT is a small molecule. Claims 62 and 63 are directed to large molecule carriers. The Alkan et al. conjugate has a structure resembling a long wire of PGA to which a plurality of small RAT carrier molecules are attached (see the Abstract – “RAT was joined to PGA by means of 6-aminocaproyl (SAC) hydrocarbon chains that extended the RAT groups out from the PGA backbone by a

maximum of 10 angstroms [PGA-(SAC-RAT)<sub>12</sub>]”). In summary, the conjugates of claims 13, 14, and 57-63 have a structure of a large carrier molecule to which a plurality of peptide ( $\gamma$ PGA) chains are attached. There is nothing in Alkan et al, Welkos et al. or Pozgay et al. that would have suggested radically transforming the basic chemical structure of the Alkan et al.

It is respectfully submitted that the application is in condition for allowance. Should there be any questions regarding this application, Examiner Swartz is invited to contact the undersigned attorney at the telephone number shown below.

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